Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0857622	12/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
San Mateo County Public Health Lab	225 37th Ave, San Mateo, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on surveyor's observation during the laboratory tour, review of records, and interview with the laboratory director (LD), technical supervisor (TS), and general supervisor (GS) on December 3, 2025; the laboratory failed to minimize possible cross contamination of patient specimens, equipment, instruments, reagents, materials, and supplies during the polymerase chain reaction (PCR) procedure. Findings include: 1. During the laboratory tour at approximately 3:00 p.m. the surveyor observed that the preparation of the master mix used in the PCR procedure was prepared in the same area/room as the template addition. 2. During an interview on December 3, 2025, at approximately 3:30 p.m., the TS and GS confirmed that the laboratory failed to minimize possible cross contamination of patient specimens, equipment, instruments, reagents, materials, and supplies during the PCR procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on December 2, 2025, stated that the laboratory performs approximately 32,000 Virology testing samples annually that include Real Time PCR molecular diagnostic tests annually.
D3005	FACILITIES CFR(s): 493.1101(a)(3) (a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

	This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the laboratory's Polymerase Chain Reaction (PCR) testing for the presumptive detection of various viral agents, interviews with the laboratory's director (LD), technical supervisor (TS), and general supervisor (GS) on December 3, 2025 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have an unidirectional flow with separate areas for specimen preparation, master mix, reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the detection of various viral agents such Monkey Pox and Respiratory Syncytial Virus (RSV) using manual methods for preparation of the Master-Mix (MM), controls and reagents, and addition of template. 2. During the laboratory tour on December 03, 2025, at approximately 3:00 p.m. the surveyor observed that preparation of reagents for the MM and sample template addition was all performed in the same room/area with no unidirectional flow. 3. The LD, TS, and GS confirmed by interview that the laboratory's molecular PCR testing was not set up following unidirectional flow. 4. Based on laboratory records, the laboratory performed and reported approximately 32,000 Virology testing samples that include Real Time PCR molecular diagnostic tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyors' observation during the laboratory's tour and interview with the laboratory's general supervisor (GS) and technical supervisor (TS) on the day of the survey, December 3, 2025, the laboratory failed to label disinfectant solution used in the laboratory to indicate, as appropriate, opening, preparation, and expiration dates when such solutions are used in the laboratory. The findings include: 1. Based on the surveyors' observation during the laboratory tour on December 3, 2025, at approximately 2:30 p.m., it was noted that the laboratory lacked labeling for the 70% Backdown Disinfectant for received, opening, preparation, and/or expiration dates, as appropriate, used throughout the laboratory. 2. The laboratory's LD and TS affirmed in an interview on December 3, 2025, at approximately 2:45 p.m., that the solution material mentioned in statement #1 above were not labeled with the reagent's date received, opening, preparation, and/or expiration dates, as applicable. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 46,303 for which the disinfectant used all throughout the laboratory was not properly labelled.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, review of the laboratory's policies and procedure, six (6) randomly selected patient records, and interviews with laboratory director (LD) and technical supervisor (TS); the laboratory failed to perform and document preventive maintenance (PM) and calibration as defined by the manufacturer and with at least the frequency specified by the manufacturer for the digital thermometers and conventional thermometers used in the laboratory. The findings included: 1. At the time of survey on December 3, 2025, based on the surveyors' observation during the laboratory tour and review of records and documentation at approximately 11:00 a.m.; it was determined that the laboratory failed to present documentation of calibration on the thermometers, both mercury and digital, for the years 2022, 2023, 2024, and 2025 for the hot plate located in bacteriology. 2. The laboratory failed to calibrate digital timers in the Panther instrument room; expired February 2, 2022, and November 2, 2023. 3. The LD and TP affirmed on December 3, 2025, at approximately 2:15 p.m. that the calibration was missed for the thermometers and digital timers for the years 2022, 2023, 2024, and 2025. 3. According to the laboratory's testing declaration submitted by the LD, the laboratory performed and reported approximately 46,302 patient samples annually for which no calibration for the thermometers or digital timers used in the laboratory in different testing areas.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, review of policies and procedures, randomly selected patient test records, and interviews with the laboratory's director, technical supervisor, and general supervisor on December 3, 2025; the laboratory director is herein cited due to failure to ensure that aspects of the preanalytic and analytic phases of the laboratory testing were monitored. The findings include See D5415 and D5429.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) (e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and This STANDARD is not met as evidenced by: Based on surveyor's observation and review of laboratory's workflow during the laboratory tour and interview with the laboratory's laboratory director, technical supervisor, and general supervisor on December 3, 2025, at approximately at 3:30 p. m., the laboratory director failed to ensure that the risk of cross-contamination was minimized during the processes for the polymerase chain reaction (PCR) testing and

	that unidirectional flow existed when PCR testing was performed. The findings include: See D3003 and D3005.